MAY 2 4 2001



UltraGuide Ltd.

510(k) Summary

MR-Guide 3000

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I. Submitter Information

A. Name: UltraGuide Ltd.

B. Address: Tirat Hacarmel Industrial Park
POB 2070
Tirat Hacarmel 30200
Israel

C. Contact Person: Dr. George Myers, 201-727-1703, Fax 201-727-1708

D. Date of preparation: January 2, 2001

II. Device Data

A. Trade Name: UltraGuide MR – Guide 3000

B. Common Name: Guiding System for Interventional Instruments for clinical interventions performed under imaging by magnetic resonance

C. Classification Name: Accessory for System, Nuclear Magnetic Resonance Imaging, 90 LNH, Regulation Number 892.1000

III. Legally marketed predicate devices.

A. Medtronics StealthStation, K001284

B. CT-Guide 1010, K002258

IV. Description

The MR-Guide 3000 provides visual guiding information of the interventional instrument by overlaying graphics depicting its relative position and its predicted future path on the MR image of the internal organs all displayed on the monitor of a personal computer.

V. Intended Use

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The MR-Guide 3000 system is a frameless stereotactic guiding accessory for Magnetic Resonance (MR) systems. The system is MRI-compatible. It displays the simulated image of a rigid insertion instrument, such as a biopsy needle or an aspiration needle, on a computer monitor screen that also shows the MR image of the target organs and the projected future path of the interventional instrument, compensating for respiratory movements of the patient.

The device is intended to be used in clinical interventions and for anatomical structures where magnetic resonance is currently used for visualizing such structures.

VI. Technological characteristics

The device uses an optical tracking system comprising infrared light source illuminating retro-reflective targets and so allow for the system 'Position Sensor' to track them, this optical tracking system sold under the trade name "Passive POLARIS System" is used to determine the location and orientation of the interventional instrument. Such optical tracking system best suited to be used in an MR environment has been used on medical devices cleared by the FDA. The position of the interventional instrument, and the MR images acquired by the MR scanner, are transmitted to a data processor (computer), which makes the necessary calculations to provide the guidance graphic overlay depicting the interventional instrument on the MRI image.

VII. Testing

A. Non-clinical tests

The MR-Guide 3000 has undergone extensive bench tests for electrical safety and electromagnetic compatibility. The major components (the computer and optical tracker) are all commercial devices with published environmental and physical specifications.

Accuracy tests were done in phantoms.

B. Clinical Test

Since this system uses the same technology as the predicate device, a clinical test is not necessary. However, scans were taken on representative patients to demonstrate the types of images obtained.

VIII. Conclusion

The tests show that the UltraGuide MR-Guide 3000 is equivalent to the predicate devices in safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2001

UltraGuide, Ltd.
% Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
PLYMOUNTH MEETING PA 19462-1298

Re: K011418
UltraGuide MR-Guide 3000
Dated: May 8, 2001
Received: May 9, 2001
Regulatory Class: II
21 CFR §892.1000/Procode: 90 LNH

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

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510(k) Number (if known): K011418

**Device Name:** **MR-Guide 3000**

**Indications for Use:**
The MR-Guide 3000 system is a frameless stereotactic guiding accessory for Magnetic Resonance (MR) systems. It displays graphics depicting the position and future path of a rigid interventional instrument, such as a biopsy needle or an aspiration needle, on a computer monitor screen that also shows the MR image of the target organs. MR-Guide 3000 system also enables monitoring the respiratory phase of the patient.

The device is intended to be used in clinical interventions and for anatomical structures where magnetic resonance imaging is currently used for visualizing such structures.

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

David G. Krogmann

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011418

**Prescription Use** ✓
**(Per 21 CFR 801.109)**